

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

HSIN LIN,  
Plaintiff,  
v.  
SOLTA MEDICAL, INC.,  
Defendant.

Case No. 21-cv-05062-PJH

**ORDER RE PARTIES' MOTIONS TO  
EXCLUDE OPINION TESTIMONY**

Re: Dkt. Nos. 112, 113, 116, 118, 119  
& 120

Before the court are (1) plaintiff's motion to exclude expert opinion testimony of Dr. Stewart Wang (Dkt. 112); (2) plaintiff's motion to exclude expert opinion testimony of Jay Bennett and Richard Malwitz (Dkt. 113); (3) defendant's motion to exclude expert opinion testimony of Monica Ip (Dkt. 116); (4) defendant's motion to exclude expert opinion testimony of Alan Schwartz (Dkt. 118); (5) defendant's motion to exclude expert opinion testimony of Dr. Christine Lee (Dkt. 119); and (6) defendant's motion to exclude expert opinion testimony of Boris Leschinsky (Dkt. 120). Although the parties filed the above motions in conjunction with defendant's motion for summary judgment, this order addresses the admissibility of the challenged expert opinions for purposes of both the motion for summary judgment and trial. The order granting in part and denying in part defendant's motion for summary judgment (Dkt. 155) did not rely on any of the opinions excluded by this order

These matters are fully briefed and suitable for decision without oral argument. Having read the parties' papers and carefully considered their arguments and the

relevant legal authority, and good cause appearing, the court hereby rules as follows.

## DISCUSSION

### A. Legal Standard

Federal Rule of Evidence 702 permits experts qualified by “knowledge, skill, experience, training, or education” to testify “in the form of an opinion or otherwise” based on “scientific, technical, or other specialized knowledge” if that “knowledge will help the trier of fact to understand the evidence or to determine a fact in issue”. Fed. R. Evid. 702. The proponent of expert testimony bears the burden of establishing by a preponderance of the evidence that the admissibility requirements are met. See id., Advisory Committee Notes.

The trial court is obliged to exercise “a gatekeeping role” regarding the admission of expert scientific testimony under Rule 702. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 597 (1993). Daubert requires a two-part analysis. First, the court must determine whether an expert's testimony reflects “scientific knowledge,” whether the findings are “derived by the scientific method,” and whether the work product is “good science”—in other words, whether the testimony is reliable and trustworthy. Id. at 590 & n.9, 593. Second, the court must determine whether the testimony is “relevant to the task at hand.” Id. at 597.

First, scientific evidence is reliable if it is grounded in methods of science—the focus is on principles and methodology, not on conclusions. Metabolife Int'l, Inc. v. Wornick, 264 F.3d 832, 841 (9th Cir. 2001); see also Stilwell v. Smith & Nephew, Inc., 482 F.3d 1187, 1192 (9th Cir. 2007) (reliability is not determined based on the “correctness of the expert's conclusions but the soundness of his methodology”). In determining whether an expert's reasoning or methodology is scientifically valid, the district court can consider “many factors” (Daubert, 509 U.S. at 593–94), including “(1) whether the scientific theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether a particular technique has a known potential rate of error; and (4) whether the theory or

1 technique is generally accepted in the relevant scientific community.” Metabolife, 264  
2 F.3d at 841.

3 Nevertheless, depending on the type of expert testimony offered, these factors  
4 may not be appropriate to assess reliability. Kumho Tire Co. v. Carmichael, 526 U.S.  
5 137, 152 (1999) (“the trial judge must have considerable leeway in deciding in a particular  
6 case how to go about determining whether particular expert testimony is reliable”). Other  
7 factors that might be considered to assess reliability include whether an expert has  
8 unjustifiably extrapolated from an accepted premise to an unfounded conclusion (see  
9 General Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997) (“[N]othing in either Daubert or the  
10 Federal Rules of Evidence requires a district court to admit opinion evidence that is  
11 connected to existing data only by the *ipse dixit* of the expert. A court may conclude that  
12 there is simply too great an analytical gap between the data and the opinion proffered.”)),  
13 or whether an expert has adequately accounted for obvious alternative explanations (see  
14 Claar v. Burlington Northern R. Co., 29 F.3d 499, 502 (9th Cir. 1994); Carnegie Mellon  
15 Univ. v. Hoffmann–LaRoche, Inc., 55 F.Supp.2d 1024, 1034–35 (N.D. Cal. 1999)  
16 (methodology may not be reliable if an expert “fail[s] to address and exclude alternative  
17 explanations for the data on which he bases his findings” or “reject[s] studies reporting  
18 contrary empirical findings”)).

19 The trial court should ensure the expert “employs in the courtroom the same level  
20 of intellectual rigor that characterizes the practice of an expert in the relevant field.”  
21 Kumho Tire, 526 U.S. at 152. The court should also consider whether an expert  
22 prepared his methodology for purposes of litigation or articulated the methodology before  
23 litigation and without any incentive to reach a particular outcome. See Daubert v. Merrell  
24 Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995).

25 Second, expert testimony is relevant if the knowledge underlying it has a “valid . . .  
26 connection to the pertinent inquiry.” Daubert, 509 U.S. at 591–92. As Rule 702 requires,  
27 it must “help the trier of fact to understand the evidence or to determine a fact in issue.”  
28 Fed. R. Evid. 702(a); see also Daubert, 509 U.S. at 591. But “scientific validity [and

relevance] for one purpose is not necessarily scientific validity for other, unrelated purposes.” Daubert, 509 U.S. at 591.

## **B. Analysis**

### **1. Plaintiff’s Motion to Exclude Opinion Testimony of Dr. Stewart Wang**

Plaintiff moves to exclude three of Dr. Wang’s four proffered opinions.

Specifically, she seeks to exclude the following:

Opinion 1. Authenticity of the Ulthera and Thermage CPT systems used during the treatment of Ms. Lin has not been established.

Opinion 2. There is no available evidence whether the transducer (Ulthera) or the treatment tip (Thermage CPT) was defective or counterfeit.

Opinion 3. Dr. Huang’s decision to perform off-label dual-device treatment under general anesthesia using higher than moderate treatment levels deviated from the standard of care and is the likely cause of Ms. Lin’s injury.

Wang Mot., Dkt. 112 at 3–4.

Plaintiff does not seek to exclude Dr. Wang’s opinion concerning “Ms. Lin’s current physical status and possible treatment options”. Wang Report, Dkt. 114-3 at 14.

#### **a. Opinions 1 and 2**

Plaintiff argues that the first and second opinions are not helpful to the jury and are not based on sufficient facts. She argues that Dr. Wang lacks sufficient qualifications to offer his third opinion. Defendant argues that Dr. Wang applied a trustworthy methodology to arrive at his first two opinions based on sufficient facts, that the opinions will be helpful to the jury, and that Dr. Wang is qualified to offer his third opinion.

Concerning Dr. Wang’s first two opinions, the court first considers whether an expert’s testimony reflects “scientific knowledge,” whether the findings are “derived by the scientific method,” and whether the work product is “good science”—in other words, whether the testimony is reliable and trustworthy. Daubert, 509 U.S. at 590 & n.9, 593. Solta explains that Dr. Wang applied his “methodology to evaluate the potential causes of Plaintiff’s injury.” Wang Opp., Dkt. 129 at 2. Dr. Wang explained that following an

adverse event, he would first ensure that genuine parts were used. That is a reasonable method, and Dr. Wang might explain the types of things he would look for to make that determination. However, his method loses trustworthiness by depending so heavily on his review of deposition transcripts to assess whether a genuine device was used. At that point, Dr. Wang no longer adhered to an established methodology, but instead conducted an ad-hoc factual inquiry based on evaluating witness testimony that is better suited to the legal than scientific process.

Second, the court considers whether the testimony is “relevant to the task at hand.” Daubert, 509 U.S. at 597. Here, Dr. Wang has not opined that the device was inauthentic, nor has he opined that the tips were defective or counterfeit. He simply characterized the state of the evidence, and in fact his opinions verge on offering bare legal conclusions. The jury must decide whether the Thermage system was authentic or not. Dr. Wang’s opinion that the available evidence does not support a finding of authenticity usurps the jury’s function of weighing the evidence and resolving a legal dispute. His opinion does not offer any new, useful information for the jury to consider—it simply seeks to substitute his judgment in place of the jury’s. Accordingly, Dr. Wang’s knowledge does not have a “valid . . . connection to the pertinent inquiry.” Id. at 592.

Because Dr. Wang’s first two opinions are neither reliably grounded in methods of science nor helpful to the jury, plaintiff’s motion is GRANTED with respect to those opinions, and they are EXCLUDED.

### **b. Opinion 3**

Dr. Wang’s third opinion concerns whether the treating physician deviated from the standard of care and is the likely cause of Ms. Lin’s injury.

“In order to testify as an expert in a medical malpractice case, a person must have enough knowledge, learning and skill with the relevant subject to speak with authority, and he or she must be familiar with the standard of care to which the defendant was held.” Avivi v. Centro Medico Urgente Med. Ctr., 159 Cal. App. 4th 463, 467 (2008), as modified (Jan. 24, 2008). “The essential factor” in determining the qualification of an

expert witness in medical malpractice cases “is knowledge of similarity of conditions; geographical proximity is only one factor to be considered.” Sinz v. Owens, 33 Cal. 2d 749, 756 (1949). “[T]he question as to what constitutes similar circumstances . . . presents an issue which concerns the competency of a person called to testify as a witness, and must be decided upon a consideration of all relevant evidence.” Id. at 755. “The Supreme Court has formulated the standard of care as that of physicians in similar *circumstances* rather than similar *locations*.” Avivi, 159 Cal. App. 4th at 468.

Accordingly, “the standard of care for physicians is the reasonable degree of skill, knowledge and care ordinarily possessed and exercised by members of the medical profession *under similar circumstances*. . . . The test for determining familiarity with the standard of care is knowledge of similar conditions. Geographical location may be a factor considered in making that determination, but, by itself, does not provide a practical basis for measuring similar circumstances.” Id. at 470–71 (admitting Israeli expert who “had numerous contacts with doctors from the United States regarding treatment of injuries similar to appellant’s, had reviewed many publications on treatment of fractures in the United States, and [concluded] that treating a fracture would be handled similarly in Israel as in the United States.” He “demonstrate[d] that he was generally familiar with the standard of care for treating fractures in the United States, and with treating fractures in circumstances similar to appellant’s.”) (citations omitted). “The unmistakable general trend in recent years has been toward liberalizing the rules relating to the testimonial qualifications of medical experts.” Borrayo v. Avery, 2 Cal. App. 5th 304, 313 (2016).

However, “there may be areas of medicine in which geographic location is especially relevant to a determination of an expert witness’s qualifications. For example, some locations may only have access to limited resources, or a particular malady may be confined to a small geographic area. In such cases, location may be a significant factor in the ‘similar circumstances’ test”. Avivi, 159 Cal. App. 4th at 471.

At deposition, Dr. Wang commented in general terms on a standard of care for cosmetic doctors. For example, he described those standards as prioritizing safety and

1 efficacy, and focusing on the patient. E.g., Wang Dep., Dkt. 114–4 at 74:15–23, 75:10–  
2 12, 102:8–21, 142:4–15. However, his description of that standard of care is so vague  
3 that it cannot be helpful to the jury. Platitudes like prioritizing safety and efficacy are not  
4 meaningful descriptions of a standard of care.

5 Concerning Dr. Wang’s qualifications to offer his opinion on the standard of care,  
6 Dr. Wang confirmed that the standards of care differ in Taiwan and the United States and  
7 that he “can’t say exactly what is their standard of care [in Taiwan, and] . . . I can’t speak  
8 on what their standard of care necessarily ought to be.” Id. at 74:8–75:9; see also Wang  
9 Report at 4 (The “standard of care for treatments using devices like Thermage . . . may  
10 vary in different parts of the world. For example, I am aware that in Taiwan and China,  
11 the use of Thermage with different forms of sedation or general anesthesia is more  
12 common and has been safely and successfully performed on patients. This is a different  
13 approach to how the treatments are commonly performed in the USA.”).

14 Because Dr. Wang confirmed both that the standard of care is different in Taiwan  
15 and that he is not qualified to describe it, he is not qualified to offer an opinion that the  
16 treating physician failed to satisfy his standard of care.

17 Accordingly, plaintiff’s motion is GRANTED with respect to Dr. Wang’s third  
18 opinion, and it is EXCLUDED to the extent it describes or otherwise opines on the  
19 standard of care or whether Dr. Huang deviated from it.

## 20 **2. Plaintiff’s Motion to Exclude Opinion Testimony of Mr. Bennett and** 21 **Mr. Malwitz**

22 Plaintiff seeks to exclude (a) Mr. Bennett’s opinions concerning the safety,  
23 efficacy, and design of the Thermage CPT; and (b) Mr. Bennett’s and Mr. Malwitz’s  
24 opinions concerning the opinions offered by plaintiff’s expert Boris Leschinsky.

### 25 **(a) Mr. Bennett’s opinions concerning the safety, efficacy and** 26 **design of the Thermage CPT**

27 Plaintiff argues that Mr. Bennett’s opinions about the product’s safety are not  
28 admissible because they are based entirely on—and are completely derivative of—the



fact that the FDA approved the product. Defendant argues his reliance on FDA clearance does not render his opinion unreliable. Upon this court's review, in every deposition excerpt concerning his assessment of the product's safety referenced by the parties, Mr. Bennett relied upon or entirely deferred to the FDA's approval as the basis for his conclusion that the product is safe. He offers no testimony concerning the device's safety based on his personal expertise or knowledge. Instead, at every opportunity he simply defers to the FDA's authority as the sole basis for his opinion. The fact that the FDA reviewed the product can be presented to the jury in a number of ways. And once that fact is before the jury, Mr. Bennett's opinion testimony concerning the product's safety would be redundant. As it is entirely derivative of another body's analysis and conclusion, Bennet's opinion on this matter does not employ any reliable methodology, nor would it help the trier of fact to understand the evidence or to determine a fact in issue. Accordingly, plaintiff's motion is GRANTED with respect to Bennet's opinion concerning the safety of the product, and the opinion is EXCLUDED.

**(b) Mr. Bennett's and Mr. Malwitz's opinions concerning the  
opinions offered by plaintiff's expert Boris Leschinsky**

Plaintiff argues that expert witnesses who do not provide written reports are limited to testifying about things they perceived during the course of the underlying events, and they cannot review materials provided to them during litigation. Defendant argues that Mr. Bennett and Mr. Malwitz are permitted to testify by offering rebuttal opinions that are based on knowledge and expertise gained from their typical job functions.

Federal Rule of Civil Procedure 26(a)(2)(B) specifies that an expert witness must provide a written report "if the witness is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony." No other expert witnesses need provide a written report. FRCP 26(a)(2)(C). Mr. Bennett and Mr. Malwitz are long-time employees of Solta who are employed there for business purposes, not to regularly give expert testimony.

Plaintiff relies on a single case—Goodman v. Staples, 644 F.3d 817, 826 (9th



1 Cir. 2011)—to support her argument that expert witnesses who do not provide written  
 2 reports are limited to testifying about things they perceived during the course of the  
 3 underlying events, and they cannot review materials provided to them during litigation.  
 4 But Goodman stands for the proposition that *retained treating physicians* need not  
 5 provide a written expert report if they are testifying about the scope of the treatment they  
 6 rendered. That case establishes an exemption to the written opinion requirement for  
 7 retained experts, not a limitation on the scope of testimony of a non-retained expert. In  
 8 fact, that court explicitly framed its holding that way. Goodman, 644 F.3d at 826 (“Today  
 9 we join those circuits that have addressed the issue and hold that a treating physician is  
 10 only exempt from Rule 26(a)(2)(B)'s written report requirement to the extent that his  
 11 opinions were formed during the course of treatment.”). Accordingly, plaintiff’s request to  
 12 exclude Mr. Bennett’s and Mr. Malwitz’s rebuttal opinions is DENIED.

### 13 3. Defendant’s Motion to Exclude Opinion Testimony of Monica Ip

14 Defendant moves to exclude the expert opinion testimony of Ms. Ip entirely, for  
 15 two reasons. First, defendant argues that Ms. Ip’s methodology is unsound because she  
 16 assumed that plaintiff should be compensated in full for all of the contracts at issue, and  
 17 she did not independently investigate to determine whether or not plaintiff should prevail  
 18 on the merits of each contract. Second, defendant argues that Ms. Ip’s methodology is  
 19 only simple arithmetic, and because it is very basic it is not helpful to the jury.

20 First, “reliance on assumptions provided by counsel or other experts is not a bar to  
 21 [damages expert] testimony.” United States ex rel. Jordan v. Northrop Grumman Corp.,  
 22 No. CV 95-2985 ABC (EX), 2003 WL 27366224, at \*6 (C.D. Cal. Jan. 6, 2003) (expert  
 23 “has performed damages calculations as an accountant, based on the review of evidence  
 24 provided by . . . other experts and assumptions provided by . . . counsel”) (citing United  
 25 States v. Soulard, 730 F.2d 1292, 1299 (9th Cir. 1984) (affirming the district court's  
 26 admission of expert testimony summarizing evidence furnished by counsel and other  
 27 experts)). Solta’s argument “fails to grapple with the fact that Stockton is a *damages*  
 28 *expert*, and, thus, is entitled to *assume* liability in order to model the damages.” Siqueiros

1 v. General Motors, Case No. 16-cv-07244-EMC, 2022 WL 74182, at \*10 (N.D. Cal. Jan.  
 2 7, 2022); see also, e.g., Indect USA v. Park Assist, Case No. 18-cv-02409-BEN-DEB,  
 3 2021 WL 4311002, at \*3 (S.D. Cal. Sept. 22, 2021) (“it is well established that experts on  
 4 damages can assume causation”); Orthofix v. Gordon, Case No. 13-cv-1463, 2016 WL  
 5 1273160, at \*3 (C.D. Ill. Mar. 31, 2016) (“It is entirely appropriate for a damages expert to  
 6 assume liability for the purposes of his or her opinion. To hold otherwise would be  
 7 illogical.”); Luitpold Pharms. v. Ed. Geistlich Sohne, Case No. 11-cv-681, 2015 WL  
 8 5459662, at \*10 (S.D.N.Y. Sept. 16, 2015) (“a damages expert does not need to perform  
 9 her own causation analysis to offer useful expert testimony”); Gaedeke Holdings v.  
 10 Baker, Case No. CIV-11-649, 2015 WL 11570978, at \*3 (W.D. Okla. Nov. 30, 2015)  
 11 (“Proof of causation often comes from fact witnesses, and it is appropriate for expert  
 12 witnesses to assume causation will be established and then proceed to calculate the  
 13 damages.”); In re Honda Idle Stop Litig., Case No. 22-cv-04252-MCS-SK, 2024 WL  
 14 4438933, at \*13 (C.D. Cal. Oct. 3, 2024) (“Defendant also takes issue with the  
 15 assumptions Plaintiffs’ expert takes to arrive at a damages estimate, but damages  
 16 experts are ‘entitled to *assume* liability in order to model the damages’”) (citation omitted)  
 17 (quoting Riddell v. Gen. Motors, Case No. 20-cv-254-SNLJ, 2024 WL 2077559, at \*2  
 18 (E.D. Mo. May 9, 2024)).

19 Ms. Ip assumed liability and calculated damages accordingly, as is permitted.  
 20 However, whether Solta is in fact liable for contract damages will be determined by the  
 21 jury, and Ms. Ip offers no opinion on that question. The reliability of the assumptions  
 22 underlying her opinion will of course impact the jury’s assessment of her ultimate opinion.

23 Second, Solta is correct that presenting only basic arithmetic can be grounds to  
 24 exclude an expert’s testimony as unhelpful. While it is technically true that Ms. Ip is  
 25 primarily presenting the results of arithmetic calculations, she has done somewhat  
 26 complex arithmetic. She has identified the lost revenue from contracts, collected dates  
 27 from the contracts that she believes represent when funds should have transferred to  
 28 plaintiff, and calculated prejudgment interest based on those dates and those amounts.

1 Finally, she has summed the lost revenue and prejudgment interest amounts.

2 While each step is relatively straightforward, the end result of her analysis certainly  
3 helps the jury assess a reasonable damages figure, so long as they agree with Ms. Ip's  
4 assumptions concerning liability. Accordingly, defendant's motion seeking to exclude  
5 Ms. Ip's testimony is DENIED.

6 **4. Defendant's Motion to Exclude Opinion Testimony of Alan Schwartz**

7 Defendant moves to exclude the opinions of Mr. Schwartz because he is not  
8 qualified; because they are based on insufficient facts and unreliable methodology; and  
9 because they are not related to any causes of action in the case. Plaintiff responds that  
10 Mr. Schwartz is qualified, and that his opinions are "reliable and relevant to Plaintiff's  
11 claims for strict liability and negligent failure to warn, as well as punitive damages"  
12 plaintiff seeks related to those causes of action. Schwartz Opp., Dkt. 132 at 7. Plaintiff  
13 also refers to Mr. Schwartz's opinions relating to "good manufacturing practices." *Id.* at 8.

14 The court has granted defendant's motion for summary judgment with respect to  
15 plaintiff's strict liability and negligent failure to warn causes of action, as well as plaintiff's  
16 manufacturing defect causes of action. Dkt. 155. In doing so, the court did not rely on  
17 any of Mr. Schwartz's opinions. As Mr. Schwartz's opinions are limited to issues  
18 pertaining to those causes of action, his testimony cannot "help the trier of fact to  
19 understand the evidence or to determine a fact in issue". Fed. R. Evid. 702(a).  
20 Accordingly, defendant's motion to exclude his opinion testimony is GRANTED.

21 **5. Defendant's Motion to Exclude Opinion Testimony of Dr. Christine Lee**

22 Dr. Lee offers two opinions:

- 23 1. Ms. Lin's Burn Injuries Were Most Likely Caused by a Thermage CPT  
24 Device Manufactured by Solta
- 25 2. Solta Failed to Adequately Warn Thermage CPT Providers of the Risks of  
26 Providing Thermage Treatment in Combination with Other Devices and of  
27 Performing Thermage Treatment Under Anesthesia

28 Lee Report, Dkt. 135-1, Ex. 3 at 3, 5.

Defendant moves to exclude the expert opinion testimony of Dr. Lee entirely. It raises five specific parts of her opinions to exclude: (a) causation; (b) that the device was genuine; (c) adequacy of warnings; (d) failure to train; (e) testing of first-generation Thermage; and (f) opinions about Solta's knowledge and intent.

**a. Causation**

Dr. Lee offers the opinion: "Ms. Lin's Burn Injuries Were Most Likely Caused by a Thermage CPT Device Manufactured by Solta". Lee Report at 3.

Defendant challenges both parts of that opinion. The first part, that Ms. Lin's burn injuries were most likely caused by a Thermage CPT device, is addressed presently. The second part, that the "Thermage CPT Device [was] Manufactured by Solta", is addressed below.

Defendant argues that Dr. Lee cannot point to any valid methodology that she used to form the opinion that a Thermage CPT caused plaintiff's burns. It argues that Dr. Lee also failed to account for obvious alternative explanations, like Dr. Huang's role in the procedure.

In determining reliability, the court assesses whether an expert has adequately accounted for obvious alternative explanations. See Claar, 29 F.3d at 502; Carnegie Mellon, 55 F.Supp.2d at 1034–35 (methodology may not be reliable if an expert "fail[s] to address and exclude alternative explanations for the data on which he bases his findings" or "reject[s] studies reporting contrary empirical findings.")).

In the medical context, "[d]ifferential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." Clausen v. M/V New Carissa, 339 F.3d 1049, 1057 (9th Cir. 2003), as amended on denial of reh'g (Sept. 25, 2003) (quoting Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999)). "While it is true that an expert properly may rely on his extensive clinical experience in making a differential diagnosis, the proper performance of a differential diagnosis involves 'first assuming the pertinence of all potential causes, then ruling out the ones as to which

1 there is no plausible evidence of causation, and then determining the most likely cause  
2 among those that cannot be excluded.” Leakas v. Monterey Bay Mil. Hous., Case No.  
3 22-cv-01422-VKD, 2024 WL 495938, at \*6 (N.D. Cal. Feb. 8, 2024) (quoting Wendell v.  
4 GlaxoSmithKline LLC, 858 F.3d 1227, 1234, 1237 (9th Cir. 2017)); see also Clausen, 339  
5 F.3d at 1057 (“Differential diagnosis is a common scientific technique, and federal courts,  
6 generally speaking, have recognized that a properly conducted differential diagnosis is  
7 admissible under Daubert.”). Thus, “[t]he first step in the diagnostic process is to compile  
8 a comprehensive list of hypotheses that might explain the set of salient clinical findings  
9 under consideration.” Clausen, 339 F.3d at 1057. “[E]xpert testimony that neglects to  
10 consider a hypothesis that might explain the clinical findings under consideration may  
11 also be unreliable.” Id. at 1058; accord Claar, 29 F.3d at 502 (expert testimony excluded  
12 where he failed to make “any effort to rule out other possible causes for the injuries  
13 plaintiffs complain of”); cf. Wendell, 858 F.3d at 1237 (“We do not require experts to  
14 eliminate all other possible causes of a condition for the expert's testimony to be  
15 reliable.”). “After the expert rules in all of the potential hypotheses that might explain a  
16 patient's symptoms, he or she must then engage in a process of elimination, eliminating  
17 hypotheses on the basis of a continuing examination of the evidence so as to reach a  
18 conclusion as to the most likely cause of the findings in that particular case.” Clausen,  
19 339 F.3d at 1058. “The expert must provide reasons for rejecting alternative hypotheses  
20 ‘using scientific methods and procedures’ and the elimination of those hypotheses must  
21 be founded on more than ‘subjective beliefs or unsupported speculation.’” Id. (quoting  
22 Claar, 29 F.3d at 502). “A district court is justified in excluding evidence if an expert  
23 utterly fails to offer an explanation for why the proffered alternative cause was ruled out.”  
24 Id. (internal quotation marks omitted).

25 This motion may ultimately rest on the parties’ different understandings of what  
26 Dr. Lee’s opinion means to convey. Solta’s motion argues as though Dr. Lee will opine  
27 that the Thermage device was the exclusive cause of plaintiff’s injury. The expert report  
28 and deposition, however, convey that Dr. Lee simply believes that Dr. Huang was using a

1 Thermage device when the injury occurred (as discussed below, she even takes no  
2 position on whether a genuine tip was being used). Dr. Lee is qualified to give this more  
3 limited opinion—that the burn occurred during treatment with a Thermage device or  
4 counterfeit Thermage device—based on her clinical experience, and her method of  
5 reviewing burn patterns and comparing them to her experience is sufficiently reliable.

6 However, Dr. Lee may not opine that the Thermage device was the sole cause, or  
7 even the primary cause, of plaintiff's burn. Dr. Lee's methodology in arriving at that  
8 opinion—to the extent she does—is not sufficiently reliable to survive the court's  
9 gatekeeping function mandated by Daubert. Dr. Lee has failed to adequately provide an  
10 explanation of the process she used to arrive at that opinion. When asked basic  
11 questions about her methodology at deposition—for example what other causes she  
12 considered—her lack of a reliable method was made readily apparent. When asked  
13 whether Dr. Huang's "malpractice" is one of the potential causes of Ms. Lin's injuries,  
14 Dr. Lee answered "Well, of course he contributed to it." Lee Dep., Dkt. 135-1, Ex. 5 at  
15 262:9. She then testified that she did not consider his potential malpractice as a  
16 contributing factor to plaintiff's injuries because "it was irrelevant" because "this is a  
17 product liability case". Id. at 262:10–16. She did not consider whether Dr. Huang was  
18 even "solely responsible because of his medical decisionmaking during Ms. Lin's  
19 treatment as the cause of her injury" because "[t]hat's not what I was asked to do." Id. at  
20 262:17–22. She expressly agreed that she did not "consider other potential alternatives"  
21 or do "a specific analysis" as to the cause of the burn, and just focused on the "specific  
22 pattern" of the burn. Id. at 146:11–149:2.

23 In fact, when asked at deposition about what her process would be to "assess  
24 whether it was the device itself that caused it or . . . some other reason", she responded  
25 that the treating physician's decisions are a critical factor:

26 Q. If you are looking at a photo of a burn that you suspect was  
27 caused or happened during a Thermage CPT treatment, is  
28 there any other information that you would need in order to  
assess whether it was the device itself that caused it or for  
some other reason?

1 A. I -- well, when you say "the device itself," I hate to sound this  
2 way, but it involves a user. So obviously, you know, I don't want  
3 to assume anything here, because you would like me to, you  
4 know, give clarity. Um, **a device doesn't burn someone, but**  
5 **the user can use the wrong settings**, use too high of a setting  
6 is usually what is most common. Usually, it's a combination, or  
7 one -- maybe it's one thing or a combination of several things.  
8 But usually, it involves using a high setting. There's something  
9 called stack pulsing, where you actually stay in the same spot,  
10 and even if you don't use a high setting, you use a low setting,  
11 but you stay in the same spot and just keep firing and firing and  
12 firing. So even with the low energy, you can burn someone if  
13 you do what we call stack pulsing.

14 . . . .

15 Q. In your experience, would you say that the typical adverse  
16 events you would see during a Thermage treatment would  
17 actually be caused by an inexperienced practitioner or  
18 someone not performing the procedure properly?

19 A. Well, it's always not performed properly, because **if it's**  
20 **performed properly, you never get a burn.**

21 Q. In fact, when you say -- I think you've said before, in  
22 materials that I've reviewed, that Thermage is a safe treatment?

23 A. Yes. I've used it myself for 20 years and I've never had a  
24 single complication, after treating thousands and thousands of  
25 patients.

26 Id. at 86:15–88:13 (emphasis added).

27 In her written report, she also explained that the treating physician's decisions  
28 contributed to the outcome:

29 In my opinion, the decision to perform a "dual-wave" procedure  
30 by combining Thermage CPT treatment with Ulthera treatment  
31 was a contributing factor to the serious injuries suffered by Ms.  
32 Lin.

33 . . . .

34 In my opinion, there is no question that a Thermage CPT can  
35 cause precisely the type of burn injuries suffered by Ms. Lin  
36 when used in the manner it was used by Dr. Huang.

37 Lee Report at 4.

38 In sum, Dr. Lee repeatedly and clearly explained that Dr. Huang's decisions were  
a critical (perhaps even sole) factor in causing plaintiff's burn. See, e.g., Lee Dep. at



249:5–13 (“most common cause of burns during a Thermage CPT treatment . . . would be classified under user error, it was the user selection of a high setting.”). Yet, she explained that her causation opinion entirely excludes his decisions as a contributing factor at plaintiff’s attorney’s direction. That renders her causation opinion—to the extent it attributes causation of the burn to the Thermage device vis-à-vis other factors—unreliable.

However, to the extent her opinion is limited to the fact that Dr. Huang was using a Thermage CPT or copycat device on plaintiff when she was burned, Dr. Lee may express that opinion based on her extensive experience and her review of plaintiff’s photographs following her treatment and burns. That opinion could also be helpful to the jury in resolving the factual dispute—if any exists—that Dr. Huang was using a Thermage CPT or copycat device on plaintiff when she was burned. This question is distinct from Dr. Lee’s opinion that the device was *genuine*, which is discussed immediately below.

Defendant’s motion with respect to this category of testimony is accordingly GRANTED IN PART AND DENIED IN PART as described above.

**b. Whether the Device Was Genuine**

Dr. Lee offers the opinion: “Ms. Lin’s Burn Injuries Were Most Likely Caused by a Thermage CPT Device Manufactured by Solta”. Lee Report at 3.

Defendant challenges both parts of that opinion. The first part was discussed above: causation. The second part, addressed here, is the opinion that the “Thermage CPT Device [was] Manufactured by Solta.”

Defendant argues that Dr. Lee’s opinion is not the result of any relevant or reliable methodology. Plaintiff argues that Dr. Lee was able to tell it was genuine based on the burn pattern, error messages displayed on the device, and the fact that counterfeit tips look different.

The relevant excerpt from Dr. Lee’s report follows:

I am aware of Solta’s claim in this case that the Thermage CPT device or treatment tip at issue may have been a counterfeit or modified product. However, I have seen no evidence to support

1 this claim. Dr. Huang testified that he had used Thermage CPT  
2 devices many times in his career before treating Ms. Lin, and  
3 that the device he used on Ms. Lin appeared and functioned  
4 like a normal Thermage CPT. Dr. Huang's testimony is  
5 supported by the fact that the treatment tip he used on Ms. Lin  
6 contained 900 energy pulses (or REPS) which is a standard  
7 number of REPS for Solta-manufactured facial treatment tips.  
8 Dr. Huang also testified that the Thermage CPT system he  
9 used showed several error messages during his treatment of  
10 Ms. Lin, including messages that required him to correct the  
11 placement and force of the treatment tip before continuing to  
12 administer energy pulses. These types of error messages are  
13 standard for Thermage CPT systems, and are unlikely to be  
14 generated by a counterfeit device.

15 Finally, I have reviewed the lease agreement provided by  
16 Dr. Yang Wei-Chen, owner of the U Beaute Clinic, showing that  
17 the Thermage CPT and treatment tips used at the clinic were  
18 rented from a third-party medical device distributor in Taiwan.  
19 Dr. Yang testified that although the Thermage CPT device was  
20 used, the treatment tips were new and individually packaged.  
21 The fact that the U Beaute Clinic did not purchase its Thermage  
22 CPT device and treatment tips directly from Solta does not  
23 indicate that these products were counterfeit. It is common  
24 knowledge in the cosmetic device industry that devices such as  
25 the Thermage CPT are frequently bought, sold, and rented on  
26 the second-hand market, particularly in Asia. While Solta may  
27 not approve of this practice as it cuts into its revenue, it is  
28 certainly aware that many of its Thermage CPT systems are  
circulating on the used market, and that the vast majority of  
these devices are not counterfeits.

Lee Report at 4–5; see also Lee Dep. at 207–229 (opining the device was genuine).

Dr. Lee supports her conclusion because: (1) Dr. Huang had used the Thermage CPT before and it appeared normal to him; (2) the device emitted 900 energy pulses, which is typical for genuine tips; (3) Dr. Huang testified that genuine error messages appeared, and those are unlikely to be generated by a counterfeit device; (4) the Thermage CPT and tips are common on the secondhand market, particularly in Asia; (5) the vast majority of second-hand devices (whether in Asia specifically or worldwide is unclear) are not counterfeit; and (6) the burn pattern was a distinctive square-shape, which Dr. Lee recognizes as caused by a Thermage CPT device.

First, the fact that Dr. Huang thought the device was genuine because it looked like others he had used is testimony properly delivered by Dr. Huang as a fact witness. Simply parroting this testimony, or deciding that it is credible, usurps the jury's function in

1 assessing testimony from a fact witness and does not constitute a reliable methodology.

2 Second, Dr. Lee considered that the device emitted 900 energy pulses, as  
3 genuine devices are designed to do. But Dr. Lee does not explain why counterfeit  
4 devices do not emit 900 energy pulses. Nor did she attempt to investigate how  
5 counterfeit devices operate, other than her general familiarity with laser devices and  
6 experience shopping for them. Critically, this opinion fails to account for or even consider  
7 an obvious alternative explanation: there may be counterfeit devices that emit 900  
8 energy pulses. Dr. Lee made no apparent effort to exclude that possibility. Although  
9 Dr. Lee testified that that she often looks at lasers (e.g., Lee Dep. at 209:25–210:6), she  
10 did not review any materials specific to this litigation, including any documents produced  
11 by Solta regarding counterfeit Thermage devices and treatment tips, or consider any  
12 other information regarding the availability of counterfeit Thermage devices (id. at 213:5–  
13 14 (opinion is based on general knowledge and online shopping for devices); id. at  
14 217:17–18 (“I did not do a literature search for this deposition or for this case.”)).  
15 Although she claims to have a general background knowledge about counterfeit devices,  
16 that sort of general experience is not replicable or testable in any meaningful way.

17 Third, Dr. Lee states that counterfeit devices do not deliver error messages, but  
18 again she offers no reliable basis for that statement other than mere ipse dixit. E.g., id. at  
19 224:19–225:18 (relying on personal knowledge).

20 Fourth, she states that genuine Thermage CPT and tips are commonly available  
21 on the secondhand market in Asia. She offers no support for that conclusion, and her  
22 “materials reviewed and considered” section offers no clues as to what might support it.  
23 Critically, FRCP 26(a)(2)(B)(ii) requires that the report contain “the facts or data  
24 considered by the witness in forming” her opinions and the basis and reasons for them.

25 Fifth, Dr. Lee stated that the vast majority of second-hand devices are not  
26 counterfeit, again with no indication at all as to what information supports that conclusion.

27 Sixth, Dr. Lee testified at deposition that the burn pattern on plaintiff’s face  
28 indicated that a Thermage device was used, but she also agreed that “if counterfeit

1 treatment tips were used during Ms. Lin's procedure, it would [probably] have left similar  
2 square-shaped pattern burns on her face". Lee Dep. at 228:10–17. Accordingly, she has  
3 presented a plausible alternative—counterfeit tip—but entirely failed to rule it out.

4 Defendant's motion with respect to this category of testimony is accordingly  
5 GRANTED, and Dr. Lee's opinions that the device or tips used during plaintiff's  
6 procedure were genuine are EXCLUDED.

7 **c. Adequacy of Warnings**

8 The court has granted defendant's motion for summary judgment with respect to  
9 plaintiff's strict liability and negligent failure to warn causes of action. Dkt. 155. In doing  
10 so, the court did not rely on any of Dr. Lee's opinions. Nor can Dr. Lee's opinions  
11 pertaining to those causes of action "help the trier of fact to understand the evidence or to  
12 determine a fact in issue". Fed. R. Evid. 702(a). Defendant's motion with respect to this  
13 category of testimony is accordingly GRANTED, and the opinions are EXCLUDED.

14 **d. Failure to Train**

15 Solta argues that any opinion concerning the adequacy of Solta's training should  
16 be excluded because plaintiff does not have a standalone failure-to-train cause of action.  
17 Plaintiff argues that Dr. Lee's opinion concerning Solta's training is relevant to rebut  
18 Solta's argument that it provides adequate warnings.

19 The court has granted defendant's motion for summary judgment with respect to  
20 plaintiff's strict liability and negligent failure to warn causes of action. Dkt. 155. In doing  
21 so, the court did not rely on any of Dr. Lee's opinions. So long as Solta does not argue  
22 that its trainings are adequate or that they in some way provide a defense to plaintiff's  
23 claims at trial, this opinion is not relevant and shall be excluded. Defendant's motion with  
24 respect to this category of testimony is accordingly GRANTED, and the opinion is  
25 EXCLUDED.

26 **e. Testing of a First-Generation Thermage Device**

27 Defendant argues that Dr. Lee should be excluded from testifying about her  
28 experience testing the first-generation Thermage device that is not at issue in this

1 litigation, including the fact that her husband was burned by one. Plaintiff does not  
2 meaningfully address this issue, other than to state that Dr. Lee has been working with  
3 Thermage devices since the first generation, and that her husband was burned by one at  
4 a medical conference. Lee Opp., Dkt. 135 at 4.

5 Dr. Lee's opinions concerning the safety and operation of the first-generation  
6 Thermage CPT device are not relevant to this litigation, and testimony to that effect shall  
7 not be permitted. However, explaining to the jury that she has been working with the  
8 Thermage CPT and its predecessor devices since their first generation provides  
9 reasonable background information to contextualize her experience for the jury. Any  
10 such testimony must be limited to explaining her background and qualifications, and not  
11 commenting on the quality or performance of those earlier devices. Specifically, the  
12 anecdote about her husband being burned at a medical conference by an earlier-  
13 generation device is irrelevant, prejudicial, and not permitted. Defendant's motion with  
14 respect to this category of testimony is accordingly GRANTED IN PART AND DENIED IN  
15 PART as described above.

16 **f. Solta's Knowledge and Intent**

17 Plaintiff argues that Dr. Lee's deposition testimony that "I think there's a monetary  
18 reason why they don't [warn against general anesthesia in the user manual]" reflects her  
19 opinion that Solta intentionally failed to warn doctors to enhance profits. Lee Opp. at 9.  
20 Plaintiff seeks to allow Dr. Lee to testify at trial that "Solta's decision not to include  
21 warnings about the risks of anesthesia in the Thermage CPT user manual was most  
22 likely motivated by financial reasons." Id. at 8.

23 As an initial matter, the court cannot locate that opinion in Dr. Lee's written report,  
24 and plaintiff does not cite to it therein. Nor does plaintiff argue that there is an amended  
25 written report containing this opinion. Accordingly, Dr. Lee cannot provide this opinion at  
26 trial. Fed R. Civ. P. 26(a)(2)(B)(i) ("The report must contain . . . a complete statement of  
27 all opinions the witness will express and the basis and reasons for them").

28 Second, the court has granted defendant's motion for summary judgment with

1 respect to plaintiff's strict liability and negligent failure to warn causes of action. Dkt. 155.  
2 In doing so, the court did not rely on any of Dr. Lee's opinions. The opinion at issue  
3 deals solely with those causes of action, and they are accordingly irrelevant and not  
4 helpful to the jury.

5 Third, the opinion fails both steps of the Daubert test. It is pure speculation, and  
6 Dr. Lee offers no methodical basis for advancing it. As pure speculation, it is not helpful  
7 to the jury, as they will be able to draw their own conclusion on the question with the  
8 same degree of expertise as Dr. Lee. This is attorney argument dressed up as an expert  
9 opinion and must be excluded. See, e.g., Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1,  
10 24–25 (1991) (Scalia, J., concurring) (“it has been the traditional practice of American  
11 courts to leave punitive damages (where the evidence satisfies the legal requirements for  
12 imposing them) to the discretion of the jury”); Anderson v. Boeing Co., Case No. 02-cv-  
13 196-CVE-FHM, 2005 WL 6011245, at \*2 (N.D. Okla. Aug. 2, 2005) (no expert “is more  
14 qualified than the average juror to make a determination whether the proof merits punitive  
15 damages, and if so, to what extent”); Voilas v. General Motors Corp., 73 F.Supp.2d 452,  
16 464 (D.N.J. 1999) (“there are no credentials that could qualify an individual as a punitive  
17 damages expert, primarily because the area of assessing punitive damages, implicative  
18 of various societal policies and lacking any basis in economics, rests strictly within the  
19 province of the jury and, thus, does not necessitate the aid of expert testimony”).

20 The parties also dispute whether Dr. Lee can opine more generally—outside the  
21 context of punitive damages—about Solta's general intent.

22 She does not offer an opinion in her report considering Solta's intent, and  
23 accordingly cannot opine at trial about Solta's intent. Nor can she opine generally about  
24 what “Solta knew”, as she offers no reliable methodology or basis for her conclusory  
25 statements to this effect, for example, that “Solta knows that the vast majority -- probably  
26 99 percent of their market -- are not doctors like me. They are doctors who don't know  
27 anything.” Lee Dep. at 123:20–23. See, e.g., Stanley v. Novartis Pharms. Corp., Case  
28 No. CV1103191JGBOPX, 2014 WL 12573393, at \*6 (C.D. Cal. May 6, 2014) (“opinions

of expert witnesses on the intent, motives, or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise”) (internal quotation marks omitted); DePaepe v. General Motors Corp., 141 F.3d 715, 720 (7th Cir. 1998) (expert “lacked any scientific basis for an opinion about the motives of [defendant’s] designers” and accordingly “could not testify *as an expert* that [defendant] had a particular motive”).

Defendant’s motion with respect to this category of testimony is accordingly GRANTED, and the opinions are EXCLUDED.

**6. Defendant’s Motion to Exclude Opinion Testimony of Boris Leschinsky**

Defendant moves to exclude the entirety of Mr. Leschinsky’s testimony, which it addressed in two general categories: opinions about (a) Thermage CPT’s design alternatives; and (b) the adequacy of the user manual, warning materials, and training.

**a. Design Alternatives**

Solta seeks to exclude a number of particular opinions Mr. Leschinsky offers concerning design alternatives: (1) that sub-surface temperature readings are a feasible design alternative; (2) that capping device output is a feasible design alternative; (3) that it would be difficult to manufacture a counterfeit device or tip; and (4) that physicians are financially incentivized to do procedures speedily.

Plaintiff argues that Mr. Leschinsky will explain (a) how the device actually works, the different energy levels of the device, and the specific temperature range that must be achieved in order to have the desired effect on the skin without causing a burn. He will explain that (b) the Thermage CPT device does not have the ability to automatically and accurately measure the subsurface temperature of a patient’s skin during treatment, so users are instructed to rely on patient feedback about the extent of their pain and discomfort during the procedure to determine the appropriate energy level. Mr. Leschinsky will opine (c) that by relying on a patient’s feedback to determine the safe and effective energy level for treatment, the Thermage CPT as designed is unreasonably



1 dangerous. Mr. Leschinsky will further opine (d) that feasible safety measures should  
2 have been implemented to protect Thermage CPT patients from foreseeable burn  
3 injuries, like a mechanism for directly and objectively measuring the temperature of a  
4 patient's subsurface tissue during treatment, and automatically capping the amount of  
5 energy delivered by the device at a safe treatment level based on this measurement.  
6 Mr. Leschinsky will testify (e) that if these safety features had been present, Plaintiff's  
7 burn injuries most likely would not have occurred. Mr. Leschinsky will also testify that  
8 (f) in the absence of an automated method for limiting the delivery of energy to a safe  
9 level, the Thermage CPT should have at least had the ability to display warnings to  
10 doctors during the procedure reminding them of the increased risk of burn injuries as the  
11 energy level is increased, particularly in the absence of patient feedback. Finally, in  
12 response to Solta's claim that the Thermage CPT system used on plaintiff may have  
13 been a counterfeit, Mr. Leschinsky will testify (g) that it would be extremely difficult, from  
14 an engineering perspective, to manufacture a counterfeit device and/or treatment tip that  
15 would operate exactly like an authentic Thermage CPT and deceive an experienced  
16 treatment provider like Dr. Huang.

17 **i. Opinions (a) and (b)**

18 With respect to opinions (a) and (b), plaintiff proposes to present Mr. Leschinsky at  
19 trial to generally explain how the Thermage CPT device works as a factual matter. Such  
20 testimony would not constitute expert opinion testimony, but instead must accord with the  
21 Federal Rules of Evidence's requirements with respect to fact witnesses. Plaintiff  
22 proposed this category of testimony for the first time in her opposition brief, and Solta's  
23 reply brief does not challenge plaintiff's ability to elicit such factual testimony from  
24 Mr. Leschinsky at trial. Plaintiff's indication of her plans to present Mr. Leschinsky as a  
25 fact witness falls outside the court's analysis under Daubert.

26 **ii. Opinion (c)**

27 Mr. Leschinsky's opinion (c)—that relying on a patient's feedback to determine the  
28 safe and effective energy level for treatment renders the Thermage CPT unreasonably

1 dangerous—is a legal conclusion. This opinion does not constitute testimony that helps  
2 the jury resolve a factual question, and it is accordingly EXCLUDED. Defendant’s motion  
3 with respect to this category of testimony is GRANTED.

4 **iii. Opinions (d), (1), and (2)**

5 In opinions (1), (2), and (d), Mr. Leschinsky proposes to opine that a reasonable  
6 design alternative would be a sub-surface skin temperature reader that automatically  
7 caps the amount of energy delivered by the device based on the measurement.

8 Solta argues that Mr. Leschinsky is not qualified as an expert by knowledge, skill,  
9 experience, training, or education because his experience with cardiac medical devices  
10 does not translate to aesthetic medical devices. Although he has worked for a company  
11 that produced “devices for wound closures” (Leschinsky Dep., Dkt. 133-1, Ex. 4 at 103:5–  
12 16), defendant argues that those devices were not “cosmetic” or “aesthetic” (id. at 129:5–  
13 13). Further, he testified that he never personally used the Thermage CPT or saw it used  
14 before visiting Dr. Lee in preparation for this litigation. Id. at 112:4–7.

15 Plaintiff argues that Mr. Leschinsky is qualified because he has worked in research  
16 and development for various medical device companies and that he has specific  
17 experience developing wound closure and cardiac devices that use radiofrequency  
18 energy for medical procedures such as tissue ablation. She argues that he is therefore  
19 familiar with the principles of radiofrequency energy delivery and how it interacts with  
20 human tissue. Id. at 100:2-12 & 107:1-9.

21 The parties primarily dispute whether Mr. Leschinsky’s experience with cardiac  
22 and wound care medical devices using radiofrequency technology qualifies him to opine  
23 on the use of similar technologies for aesthetic ends. See id. at 100:2–12 & 333:3–6  
24 (describing experience in medical settings). The relevant opinion in his expert report is  
25 that the Thermage device should measure subskin temperature, and it could do so by  
26 inserting microneedles into the skin or by copying the mechanism used by a competitor  
27 device called the Exilis. See Leschinsky Report, Dkt. 133-1, Ex. 3 at 34. However,  
28 Mr. Leschinsky abandoned that opinion at deposition. Leschinsky Dep. at 281:23–282:7

1 ("I'm not advocating for using microneedles as the method of providing a higher safety  
2 profile for the device. You asked me about other devices on the market, and one of them  
3 uses microneedles. That's the extent of what I know. And I did not use them as the  
4 example of what the Thermage system could have done."). Later, when explaining the  
5 Exilis device, he admitted that he does not understand how it works at all, and concluded  
6 that "I don't quite understand the magic, but I don't see any reason not to believe that  
7 what they're doing is effective. So it is possible to do that. That's all I'm saying at this  
8 point." Id. at 284:24–285:3; see generally id. at 276–294.

9 At bottom, Mr. Leschinsky has by his own admission no expert knowledge  
10 concerning the relevant market, how competing products are designed, how those design  
11 features work, and what tradeoffs they entail. See, e.g., id. at 285:16–24 ("So all I'm  
12 saying here is that a way exists. And so if one company figured out the way, then  
13 another company can figure out a way also."). Mr. Leschinsky calls upon no expert  
14 knowledge or methodology when asserting this opinion. Ultimately, while Mr. Leschinsky  
15 may be knowledgeable about the general radiofrequency technology used in laser  
16 skincare products, the method he employed to opine on specific design alternatives is not  
17 a reliable scientific exercise based on his expertise or understanding of the technology.  
18 Defendant's motion with respect to this category of testimony is accordingly GRANTED,  
19 and the opinion is EXCLUDED.

#### 20 **iv. Opinion (e)**

21 Mr. Leschinsky's opinion (e)—that if his preferred safety features had been  
22 present, plaintiff's burn injuries most likely would not have occurred—is not based on any  
23 sound scientific principles in which he is an expert. He is an engineer, not a physician.  
24 Moreover, he stated at his deposition that he would not opine on medical causation: "Q.  
25 You will not be offering any medical causation opinion in this case; correct? A. Correct."  
26 Id. at 101:13–15. Defendant's motion with respect to this category of testimony is  
27 accordingly GRANTED, and the opinion is EXCLUDED.

#### 28 **v. Opinion (f)**

1 Mr. Leschinsky's opinion (f)—that the device should have displayed warnings for  
2 doctors during treatment—is not based on any sound scientific principles that  
3 Mr. Leschinsky can offer expert insight into. He is not a doctor who uses similar  
4 machines, and there is no indication that he has any specialized knowledge as to how  
5 doctors use these machines and interpret warnings. Defendant's motion with respect to  
6 this category of testimony is accordingly GRANTED, and the opinion is EXCLUDED.

7 **vi. Opinions (g) and (3)**

8 In opinions (3) and (g), Mr. Leschinsky proposes to opine that it would be difficult  
9 to manufacture a counterfeit device and/or treatment tip that would deceive an  
10 experienced treatment provider like Dr. Huang.

11 The court first assesses whether the opinion is reliable and trustworthy. The focus  
12 is on whether the principles and methodology are grounded in methods of science. Solta  
13 argues that Mr. Leschinsky has not identified any scientific basis for this opinion, and that  
14 he has never even worked on a Thermage CPT system or a Thermage CPT treatment  
15 tip. Plaintiff argues that Mr. Leschinsky is an engineer who has built medical devices  
16 before, so he is able to assess whether making a counterfeit one is hard.

17 The court is unable to determine what method Mr. Leschinsky even claims to use  
18 in opining that building a counterfeit unit or tip is difficult. At the time of his deposition, he  
19 admitted that he "never worked on a Thermage CPT system or a Thermage CPT  
20 treatment tip". Id. at 305:23–306:4. When asked if he had "closely evaluate[d] the  
21 treatment tip" when he had the opportunity to view the unit with Dr. Lee, he answered  
22 simply: "I looked at it." Id. at 306:5–8. He proceeded to explain that he believes making  
23 a counterfeit tip is difficult based on his experience building medical devices. He also  
24 stated that he has never seen a counterfeit tip, that he knows they exist, that Dr. Lee has  
25 seen them, and that "[g]iven time and effort, there are experienced companies out there  
26 that can produce [counterfeit tips]." Id. at 308:7–309:18. He also stated that even if  
27 counterfeit tips are being used, it would not change his opinion because "if somebody  
28 takes the trouble of actually replicating the tip to the same degree that a company makes

1 it, I would assume it will perform in a similar manner. The issue here is not the  
2 performance of the tip. The issue here is reliance on warnings from the patient which did  
3 not happen, so that has nothing to do with the tip.” Id. at 310:13–311:1.

4 The court is left to guess at what method—if any—Mr. Leschinsky used to arrive at  
5 his opinion that “it would be exceedingly difficult to produce a counterfeit tip”. Leschinsky  
6 Report at 35. Moreover, Mr. Leschinsky has also opined that counterfeit tips exist, and  
7 that counterfeit tips are made so well that they perform similarly to genuine tips.

8 Second, the court assesses whether the opinion is helpful to the jury.  
9 Mr. Leschinsky proposes to generally opine that it is hard to make counterfeit tips. But he  
10 concedes that such tips are made, and that they are made so well that they do not impact  
11 efficacy of treatment. But if all parties agree that counterfeit tips are made, available, and  
12 at times used, an opinion that it is hard to make them does not help the jury resolve any  
13 factual question that is relevant to the case. The relevant question is whether a  
14 counterfeit tip was used during plaintiff’s treatment. And an opinion that counterfeit tips  
15 are available but difficult to make is entirely irrelevant to the question before the jury:  
16 whether the tip used on plaintiff was genuine. Defendant’s motion with respect to this  
17 category of testimony is accordingly GRANTED, and the opinion is EXCLUDED.

18 **vii. Opinion (4)**

19 Mr. Leschinsky’s opinion (4)—that physicians are financially incentivized to do  
20 procedures speedily—is not grounded in any scientific principles or methods in which  
21 Mr. Leschinsky is an expert, and it is no more helpful to the jury than lay testimony.  
22 Defendant’s motion with respect to this category of testimony is accordingly GRANTED,  
23 and the opinion is EXCLUDED.

24 **b. Adequacy of Warning Materials**

25 First, plaintiff has not opposed defendant’s motion with respect to Mr. Leschinsky’s  
26 opinions about the adequacy of defendant’s user manual, warning materials, and training.

27 Second, plaintiff offers no explanation as to the methodology used to reach these  
28 opinions, and the court is unable to discern any basis for finding that the opinions are

1 reliable or trustworthy. For example, Mr. Leschinsky opines that the warnings are  
2 inadequate because they are “vague and ambiguous”, but there is no explanation as to  
3 what method was used to reach that opinion. Id. at 30. He also opines that because  
4 Solta fails to warn, “some doctors continue to administer narcotic pain medications and/or  
5 anesthetics to their patients during Thermage CPT treatment”. Id. at 32. But that factual  
6 assertion—whether and how often doctors use anesthesia—is simply offered in his report  
7 with no explanation as to how the opinion was reached.

8 Third, those opinions are not helpful to the jury to understand the evidence or to  
9 determine a fact in issue. The court has granted defendant’s motion for summary  
10 judgment with respect to plaintiff’s strict liability and negligent failure to warn causes of  
11 action, which are the causes of action to which these opinions might relate. Dkt. 155. In  
12 doing so, the court did not rely on any of Mr. Leschinsky’s opinions.

13 Accordingly, defendant’s motion is GRANTED with respect to Mr. Leschinsky’s  
14 opinions about the adequacy of defendant’s user manual, warning materials, and training.

### 15 CONCLUSION

16 For the foregoing reasons, plaintiff’s and defendant’s motions are GRANTED IN  
17 PART AND DENIED IN PART. Plaintiff’s motion to exclude opinion testimony of  
18 Dr. Stewart Wang is GRANTED IN PART AND DENIED IN PART. Plaintiff’s motion to  
19 exclude opinion testimony of Mr. Bennett and Mr. Malwitz is GRANTED IN PART AND  
20 DENIED IN PART. Defendant’s motion to exclude opinion testimony of Ms. Ip is  
21 DENIED. Defendant’s motion to exclude opinion testimony of Mr. Schwartz is  
22 GRANTED. Defendant’s motion to exclude opinion testimony of Dr. Lee is GRANTED IN  
23 PART AND DENIED IN PART. Defendant’s motion to exclude opinion testimony of  
24 Mr. Leschinsky is GRANTED IN PART AND DENIED IN PART.

25 **IT IS SO ORDERED.**

26 Dated: December 23, 2024

27 /s/ Phyllis J. Hamilton

28 PHYLLIS J. HAMILTON  
United States District Judge